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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/694,376

10/27/2003

Allen J. Brenneman

MSE #2650

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03/11/2008

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EXAMINER

TURK, NEIL N

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/694,376 | Applicant(s) BRENNEMAN, ALLEN J. | |
| | Examiner NEIL TURK | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-14 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-14 and 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/6/07 and 10/27/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on December 6th, 2007. Claims 1-6, 8-14, and 21-27 are pending. Claims 7 and 15-20 have been cancelled. Claims 25-27 are newly added. Any objection/rejection not repeated herein has been withdrawn by the Office.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 recites the limitation "the reagent". There is insufficient antecedent basis for this limitation in the claim.

Claim 11 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The input light guide height and light transmission segment height are indefinitely recited. Claim 11 recites that the input light guide height extends from a bottom surface to a top surface, and the light transmission segment extending from a bottom surface to a top surface. The bottom and top surface of what? Applicant has not established structural surfaces, walls, or otherwise to the light guides or light transmission segment recited. Applicant must positively establish structure to the light guides and transmission segments so as to give them their heights

from one surface to another. This is likewise seen in claims 22-24 with respect to the venting cavity width and main cavity width. The first and second sides are indefinitely recited as no such structure has been established with the respective portions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8, 11, 13, 14, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (4,803,992).

Lemelson discloses a catheter or device 10 with an elongated housing 11 (lid with respect to claim 1) that includes a cable 21 that is formed of four separate light pipes 22 (enclosed input light guide of light pipe 22 and enclosed space of catheter walls between light pipe exit and the reflector), 24, 26, and 28 (enclosed output light guide of light pipe 28 and enclosed space of catheter walls between reflector and light pipe 28 inlet). Lemelson further discloses that a cavity 16 is formed in the front end portion 13 that allows light energy to be directed therethrough to scan fluent material, such as body fluid existing in the cavity (line 38, col. 3 – line 2, col. 4; fig. 1). Lemelson also discloses that the device contains a plurality of reflecting surfaces 14 (input

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reflector) and 15 (output reflector) for respectively receiving light energy passed through the lens 23 of light pipe 22 from a source light and is then directed to reflect off reflecting surface 15 to receiving lens of the light pipe 28 along which it passes to a photoelectric detector coupled to the other end of light pipe 28 (lines 3-54, col. 4).

Claims 1-5, 8, 10, 11, 13, 14, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Meserol (EP 0254246 A2).

Meserol discloses an improved cuvette. Meserol discloses a cuvette 10 in combination with a lancet 12, where the cuvette has a top 14 (lid) and a bottom 15, closed wall 18, access slot 20 (venting channel connected to the cavity), and a cavity 22 (for fluid, such as blood) (lines 25-40, col. 4, figs 1-4). Meserol discloses that the cavity 22 may be filled with a medium such as an optically transparent gel provided with a reagent test system (lines 8-21, col. 5). Meserol also discloses integrally formed optical elements, such as light beam 30 from source 32, which passes through the cuvette (enclosed input light guide is defined in the optically transmissive portion of the cuvette where light enters from source 32, and is enclosed within the walls of the cavity 22) and is reflected by reflecting prism 50 (input reflector at about 45 degrees to the input light path) across cavity 22 to reflecting prism 48 (output reflector) and back out through the sample cuvette (enclosed output light guide is defined in the optically transmissive portion of the cuvette where light is reflected back into enclosed area of cavity and out of the cuvette) to optical element 36 (lines 1-42, col. 5; lines 10-41, col. 6, figs 5&6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Naka et al. (6,001,307), hereafter Naka.

Meserol has been discussed above.

Meserol does not disclose reagent provided on the lid.

Naka discloses an optical analyzing device in which when the covering 5a is transparent and light may be irradiated through the covering, a reagent film impregnated

with a reagent may be stuck on the inner surface of the covering 5a (lines 38-46, col. 10, fig. 1a-b).

It would have been obvious to modify the Meserol device to include reagent provided on the lid such as taught by Naka, such that it would be obvious to place the reagent on the lid (or any location), in which location the reagent will come into contact with the sample solution as desired.

Claims 12 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol.

Meserol has been discussed above.

Meserol does not disclose the specific dimension of the light guide, light transmission segment, main cavity, and venting cavity as recited in the above claims.

It would have been obvious through routine experimentation to optimize the Meserol device to the dimensions as recited in the claims in order to provide an optimal light path through the device.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lundsgaard et al. (5,525,518), hereafter Lundsgaard.

Meserol has been discussed above.

Meserol discloses a lancet for obtaining a sample, but does not disclose that the lancet has a second end which deposits the sample into the cavity.

Lundsgaard discloses a needle 20 and sampling cavity connected for determination of a blood gas parameter in which the needle draws a blood sample through aperture 21 and into the conduit 21 down through measuring chambers 300, 400, 500, 600 (lines 52-67, col. 7, fig. 3).

It would have been obvious to modify the Meserol device such as taught by Lundsgaard to provide the other end of the lancet for deposition of the sample into the cavity in order to allow for direct sample deposition on to the test area, so as to avoid any loss of sample incurred from taking the pierced patient's skin and wiping sample into the cavity.

Response to Arguments

Applicant's arguments filed December 6th, 2007 have been fully considered but they are not persuasive.

With regards to claims 1, 3-5, 7, 8, 11, 13, and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson, Applicant traverses the rejection. Applicant argues that Lemelson's light pipe is not an enclosed optical communication path because of the space between the end of the light pipe 22 and the reflecting surface 14. Applicant similarly argues that the end (with lens 29) of the light pipe 28 is not an enclosed optical communication path with reflecting surface 15. Examiner argues that both are enclosed optical communication paths, as each path is enclosed and the space between the respective ends and reflectors is enclosed by the walls 12 of the housing 11 of the device (Fig. 1). Applicant also argues that Lemelson does not include a

reagent in the format. Examiner asserts that Lemelson discloses a cavity in which bodily fluid exists therein to be examined, and such a bodily fluid reads on a reagent in the format, and more specifically a reagent within the sample cavity (line 63, col. 3 - line 2, col. 4). Further, the respective dependent claims are maintained rejected as no such deficiencies exist in Lemelson with respect to the independent claims. Newly added claims 25 and 27 are rejected for the same reasons as discussed above.

With regards to claims 1-5, 7, 8, 10, 11, 13, and 14 rejected under 35 U.S.C. 102(b) as being anticipated by Meserol, Applicant traverses the rejection. Applicant argues that Meserol does not disclose any input or output light guide, let alone the claimed input and output light guides. Examiner argues that Meserol discloses an input light guide defined in the optically transmissive portion of the cuvette where light enters from source 32 and is reflected by reflecting prism 50 (input reflector). Examiner further argues that Meserol discloses an output light guide defined by the optically transmissive portion of the cuvette where light is reflected back by prism 48 (output reflector) and out through optically transmissive portions to the optical element 36. Examiner asserts that Applicant has not recited any structure to define the light guide by means of any walls, surfaces, or otherwise. As such, the optically transmissive portions of the cuvette act as a light guide as light is guided through the portions to the respective reflectors and back out through optically transmissive portions that guide the light. Further, both such input and output light guides are said to be enclosed optical communication paths. Examiner argues that in both light guides, the paths are defined in enclosed areas. Light enters

through the optically transmissive portion proximate to the source 32, where it is then enclosed with the walls of cavity 22, and thereby enters an enclosed area where it strikes reflector 50. This is likewise seen in the second portion of the light path (the output light guide), where the light is enclosed in the area where light strikes at reflector 48, passes into cavity 22 where it is enclosed by its walls, and then enters the last portion of the optically transmissive cuvette (fig. 5&6, column 5-7). Further, the respective dependent claims are maintained rejected as no such deficiencies exist in Meserol with respect to the independent claims. Newly added claims 25-27 are rejected for the same reasons as discussed above.

With regards to claims 6 and 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Naka, Applicant traverses the rejection as claims 6 and 9 depend upon independent claims 1 and 8, respectively. Examiner argues that as there no such purported deficiencies in Meserol with respect to claims 1 and 8, claims 6 and 9 are maintained properly rejected as discussed above.

With regards to claims 12 and 22-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol, Applicant traverses the rejection as claims 12 and 22-24 depend upon independent claim 8. Examiner argues that as there no such purported deficiencies in Meserol with respect to claim 8, claims 12 and 22-24 are maintained properly rejected as discussed above.

With regard to claim 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lundsgaard, Applicant traverses the rejection as claim 21 depends from independent claim 8. Examiner argues that as there no such purported deficiencies in Meserol with respect to claim 8, claims 21 is maintained properly rejected as discussed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill A. Warden/
Supervisory Patent Examiner, Art Unit 1797